

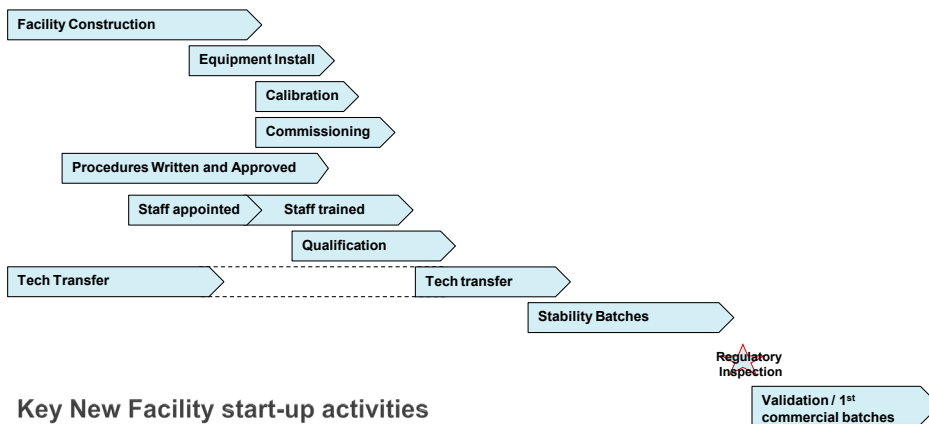
Driving the Pharmaceutical and Biotech Industries towards Excellence in Manufacturing, Supply and Quality

NEW MANUFACTURING SITE START-UPS

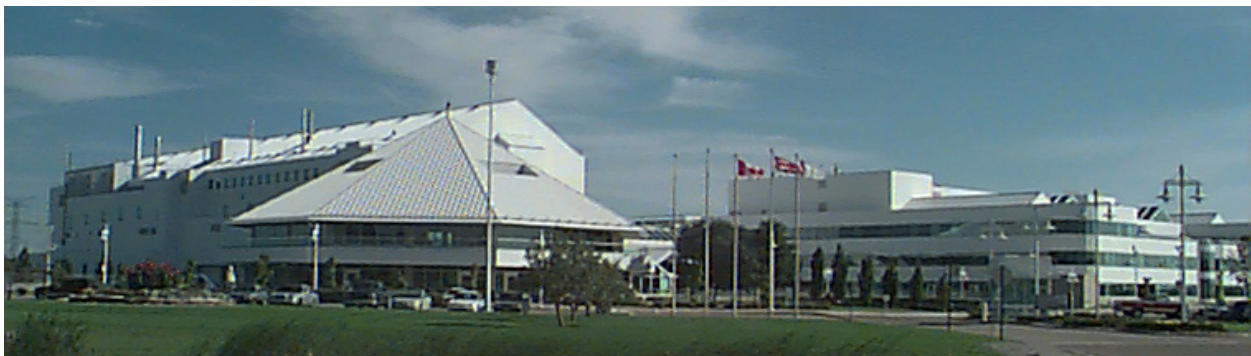
NDA consultants have had leadership roles in establishing new manufacturing sites globally. We have helped pharmaceutical companies start up operations in North America, Asia, Europe, and Africa.

Based on our proven experience we can help you build the team who will run the new manufacturing operation, install and qualify the equipment required, develop the procedures and policies required to operate it, and train the staff who will make it happen.

Through our network of Consultants, Strategic Partners and Associates we are able to provide experienced project managers, engineers and operations staff to kick start any new manufacturing site.



Key New Facility start-up activities



NEW MANUFACTURING SITE START-UP CASE STUDY

ISSUE:

A Contract Manufacturing Organization (CMO) was in the process of constructing a new manufacturing site and wanted to start-up manufacturing in the facility as quickly as possible.

OBJECTIVE:

Establish the program of work required to start-up operations in the new facility and gain regulatory approval as quickly as possible.

DELIVERABLE:

Worked with the CMO's functional staff to establish teams to quickly identify and plan the activities required to start-up a new facility. Work included;

- Equipment installation and calibration.
- Facility and equipment commissioning.
- Procedure authoring and approval.
- Facility and equipment qualification.
- Staff recruitment and training.
- Technical transfer.
- Stability batch manufacture and testing.
- Logistics transfer.
- Compliance and inspection readiness.
- Regulatory inspection and approval.
- Process validation and first commercial supply from new site.

Provided CMO's program management office with a fully loaded schedule of activities that clearly showed the tasks to be performed and the resources required to undertake the work.

Provided expertise to support the CMO's staff start-up of the new facility as required.

Contact Us

To learn more about how Nick Davies & Associates LLC (NDA) can help you, please contact us:

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